EXHIBIT 5

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Effect of Heated-Air Blanket on the Dispersion of Squames in an Operating Room: BH 505 Case Study

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Contents

1 Introduction

The objective of the present report is to describe the results of large eddy simulations (LES) of the flow in an operating room in which the Bair Hugger (BH) blower model 505 warming unit and blanket are used to heat a virtual patient. The LES method details have been described in an earlier report and also recently published as (1) in which the BH blower model 750 was used. The same operating room and inlet air conditions are used in both studies.

2 Computational Details

2.1 Air velocity and temperature conditions

Keeping the computational grid and all other flow parameters same as the BH750 study (1), a new computation was performed wherein only the blower settings were changed. This new computation was performed to study the effect of BH505 blower flow rate and its hot air temperature on the flow fields as well as the dispersion of squames.

Table 1: Flow and temperature conditions

Parameter	BH750 Case Study	BH505 Case Study
Inlet grilles air volume flow rate $\dot{V}$, [m^3/s]	1.1044	Same
Temperature of inlet grille air, [°C]	15	Same
Mean inlet velocity [m/s], $\overline{U}_{in}$	0.1933	Same
BH blower volume flow rate $\dot{V}_{blower}$, [m^3/s]	0.021	0.01416
Temperature of hot air injected along drape, [°C]	41.11	39.73
Heads of the surgeons and patient, [°C]	31.44	Same
The patient's knee , [°C]	37.78	Same
Two surgical lamps, [°C]	93.92	Same

The above table shows that in the present study, the blower volume flow rate was lowered by 32.57% compared to the BH750 study. The temperature of the hot air injected along the drape was also lower by about 3.35%. The details of calculating this temperature are given in the Appendix A of this report. Since the hot air temperature is not significantly different, the lower flow rate of the BH505 blower simply leads to a smaller velocity of the air coming out along the drape edges and slightly lowers the turbulence intensity of the rising plumes. This increases the time required for the plumes to rise and reach the operating table and thus a longer duration calculation was necessary to accurately capture the dispersion of squames.

Starting from the established velocity, density, temperature and pressure fields for the case with the blower-off, the blower was turned on. A calculation was performed for about 45s (400h computing time) to obtain a developed plume from the hot air discharged by the blower. Flow statistics and the initial location of 3 million squames particles were initiated. With the blower-on, the particle trajectories were calculated for about 45s (400h computing time).

2.2 Initial locations of the squames

Similar to the BH750 study (1), the individual trajectories of 3 million squames were computed in the present study. In order to provide a least probable scenario for the squames to be carried to the surgical site by the air convection, all 3 million squames were initially placed on the floor and

randomly distributed in a small region surrounding the operating table within a height of 1 cm above the floor of the OR.

Table 2: Coordinates of color-coded regions for initial positions of squames.

Color-coded initial position	$(x,y,z)_{min}$ [m]	$(x,y,z)_{max}$ [m]
Red	(-1.40, -0.025, 0.0)	(0.70, 0.40, 0.01)
Green	(-1.80, -1.35, 0.0)	(-1.4, 0.4, 0.01)
Yellow	(-1.40, -1.35, 0.0)	(0.70, -0.855, 0.01)

The region where the particles were located is around the OT, surrounding the feet of four surgeons present in the CAD model. To better visualize the trajectories the squames from different initial locations, the U-shaped region was divided into three rectangular sections color-coded as (i) red, (ii) green and (iii) yellow. One million squames were placed in each of the three sections at the same time, providing equal probability for the statistical analysis of motion of squames. The position of an individual squame particle in a section was chosen randomly using a uniform distribution. The squames of each section were tagged with distinct IDs. The actual coordinates of the three sections are given in Table 2.

3 Results

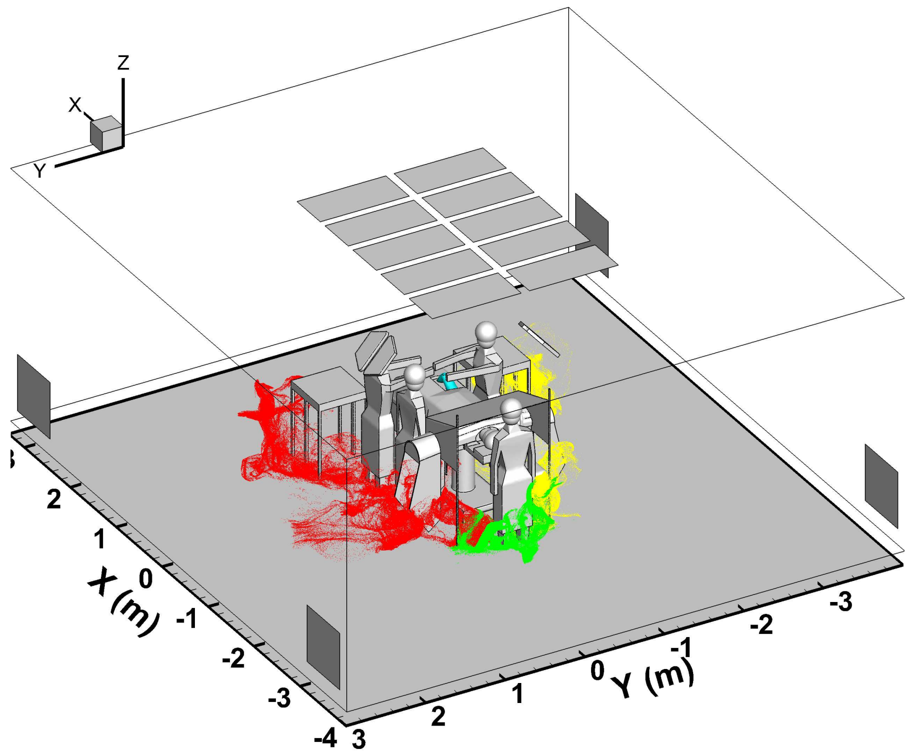
3.1 Trajectories and snapshots of squames

In order to visualize the effect of the hot blower air on the trajectory of squames, instantaneous scatter plots of squames are displayed at 10s and 20s after their initiation with blower-off and blower-on in figures 1a,b and 2a,b, respectively. The squames are also color-coded based on their region of origin. Significant differences between the blower-off and blower-on cases are observed. It is clear from figures 2a that for the blower-off case the majority of the squames are dispersed by the ventilation air flow towards the outlet grilles. None of the squames actually rise to the level of the side tables or the OT. In contrast, in the case of blower-on, a large number of squames are lifted upwards by the rising thermal plumes. Some of the squames (mostly red-colored and some yellow-colored) are lifted above the surgeons heads and are blown towards the OT by the incoming ventilation air. Large number of squames are seen to be above the OT, several are surrounding the surgeons hands, above the side tables, and some are very close to the patient's knee and the surgical site. This is better visualized by the zoom-in view shown in figures 3a,b.

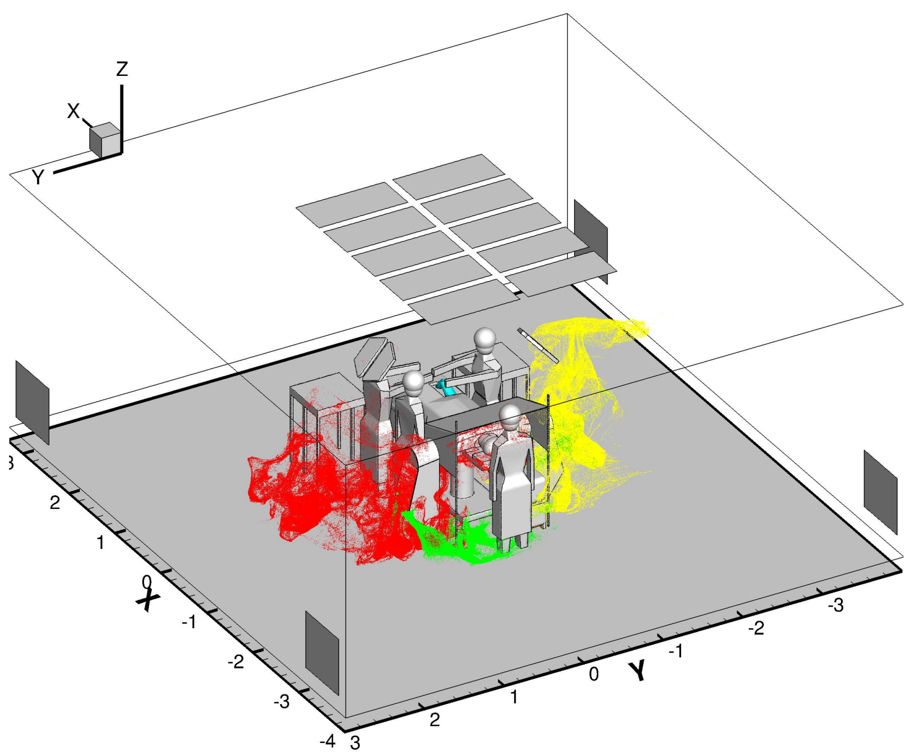
Figures 4, 5, and 6 show a different view angle for the squames at the same time instances as in the above discussion. It is again seen that with the blower-on several particles are lifted upwards by the thermal plumes and rise above the operating table and then are blown downwards by the incoming ventilation air.

Finally, figure 7 shows an instantaneous snapshot of squames very close to the patient's knee showing several squames very close to the surgical site at a time of 36s since the initiation of the particle tracking. Several particles are still suspended above the OT and are being transported downwards by the ventilation air and may potentially reach close to the surgical site.

Overall all the above results are very similar to those of the BH750 study (1), except that it takes longer time for the particle to disperse and reach the OT and the surgical site, owing to the lower flow rate of the hot air of the BH505 blower.

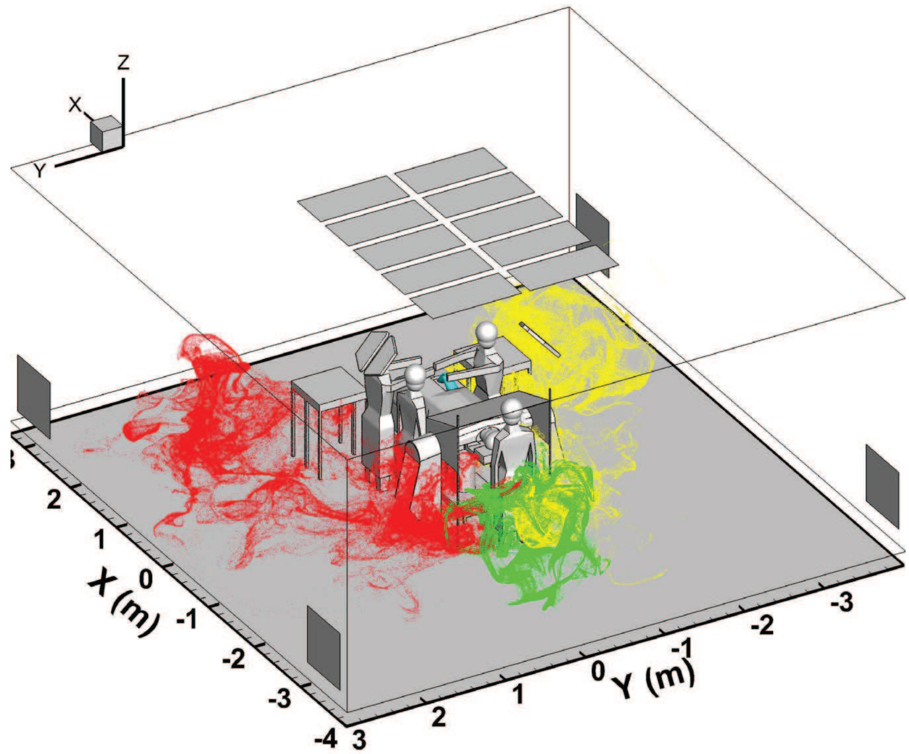


(a)

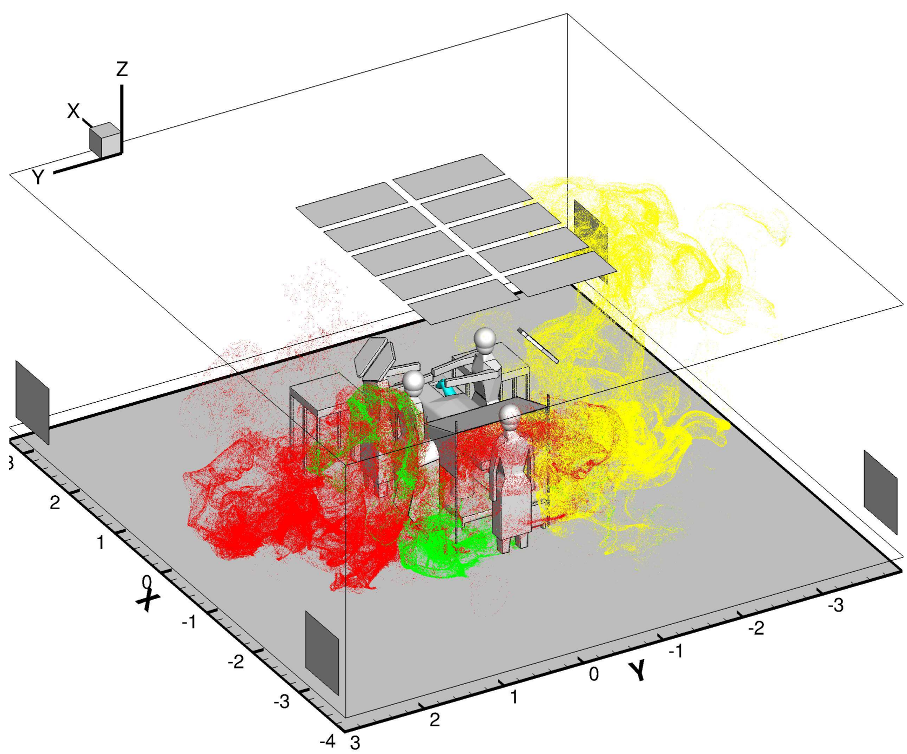


(b)

Figure 1: Instantaneous scatter plot of squames color-coded by their region of origin at 10s after initiation: (a) blower-off, (b) blower-on.

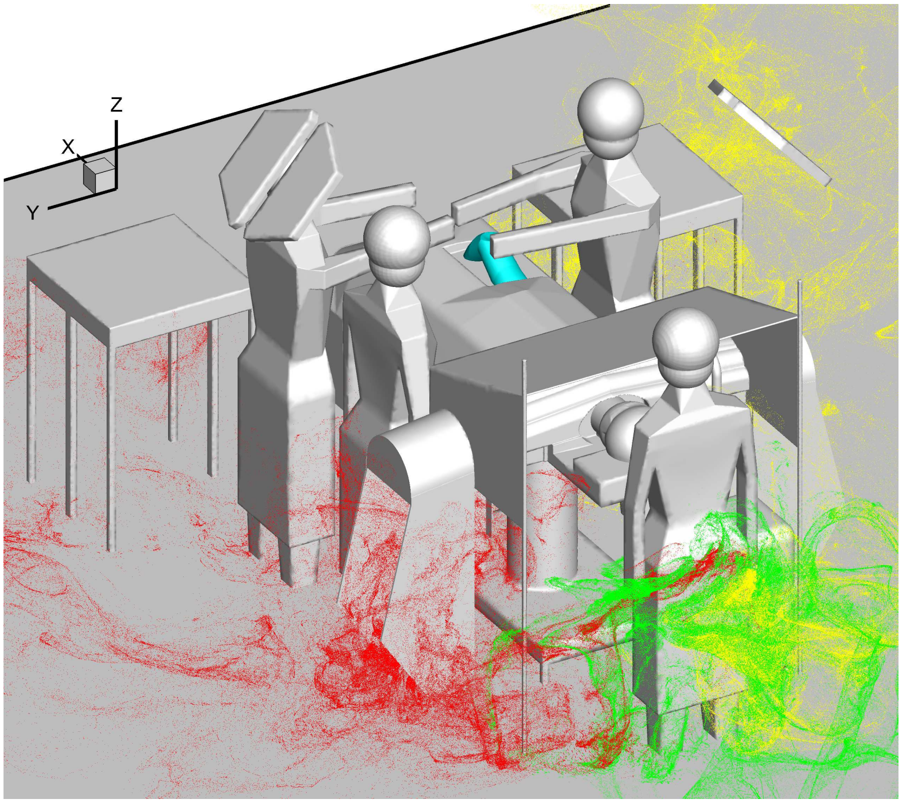


(a)

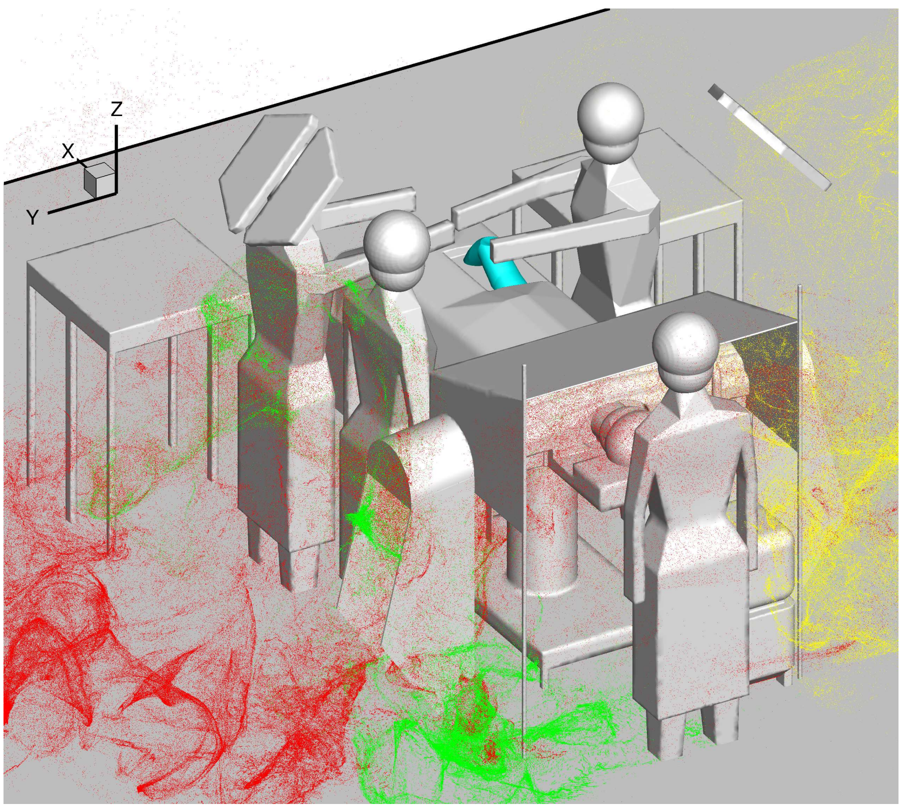


(b)

Figure 2: Instantaneous scatter plot of squames color-coded by their region of origin at 20s after initiation: (a) blower-off, (b) blower-on.

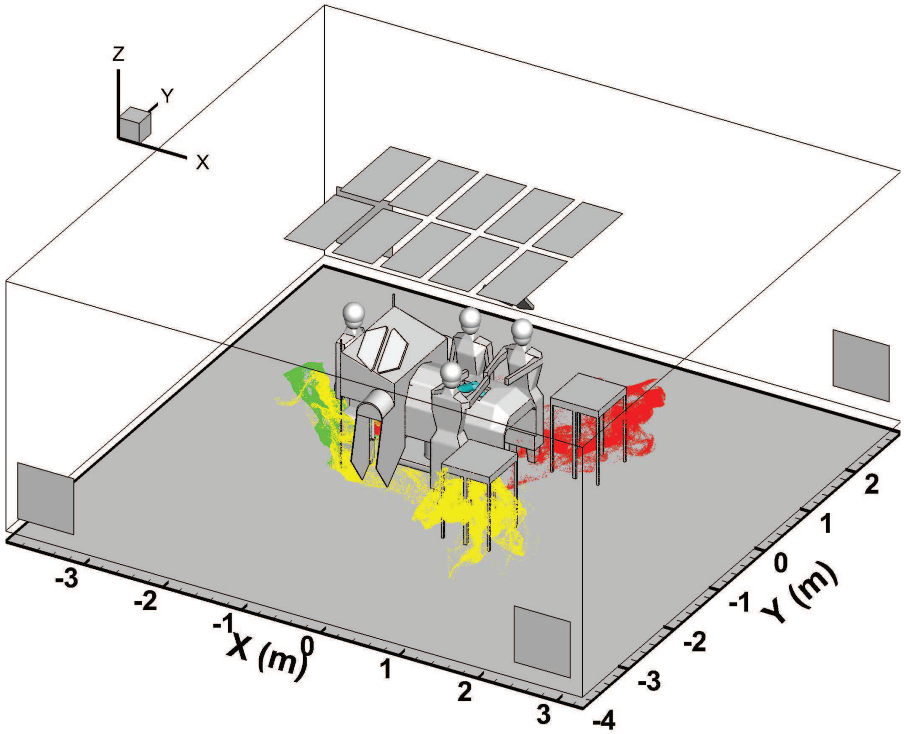


(a)

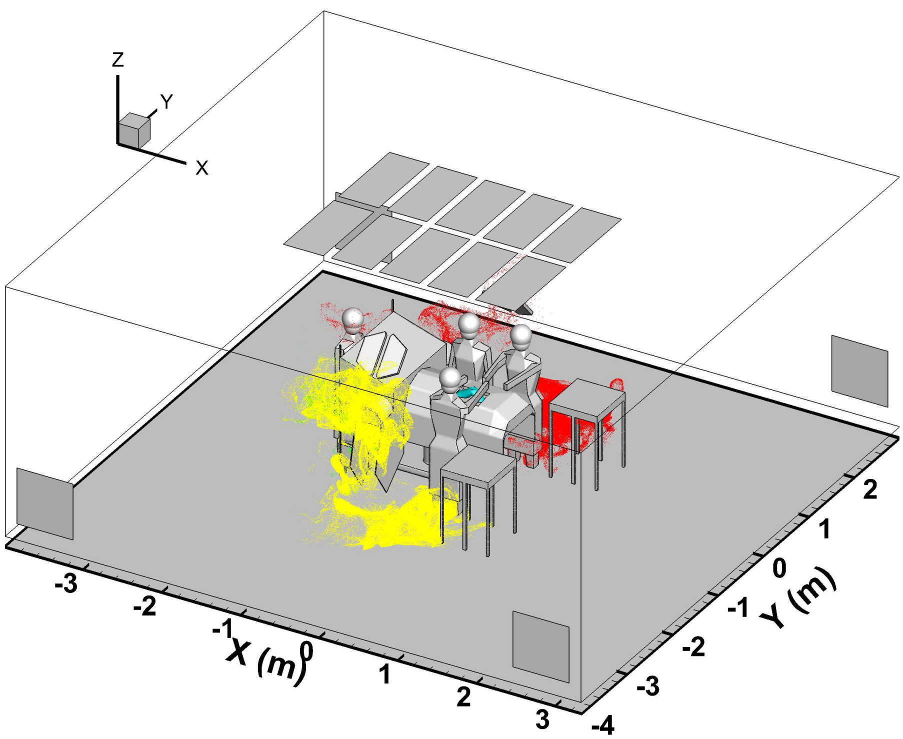


(b)

Figure 3: Zoom-in of the instantaneous scatter plot of squames color-coded by their region of origin at 20s after initiation: (a) blower-off, (b) blower-on.

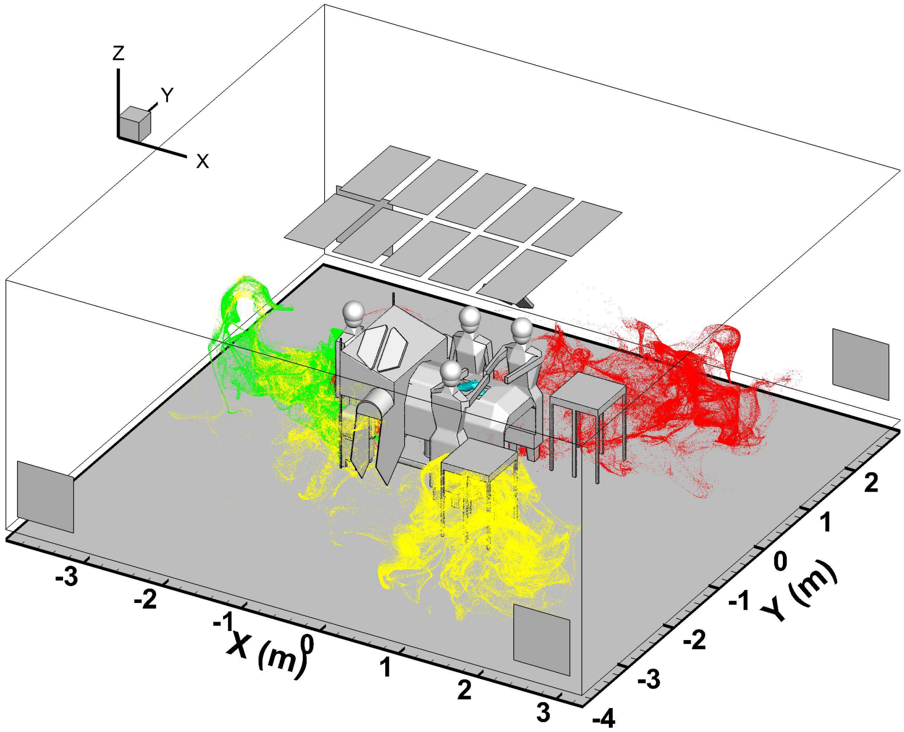


(a)

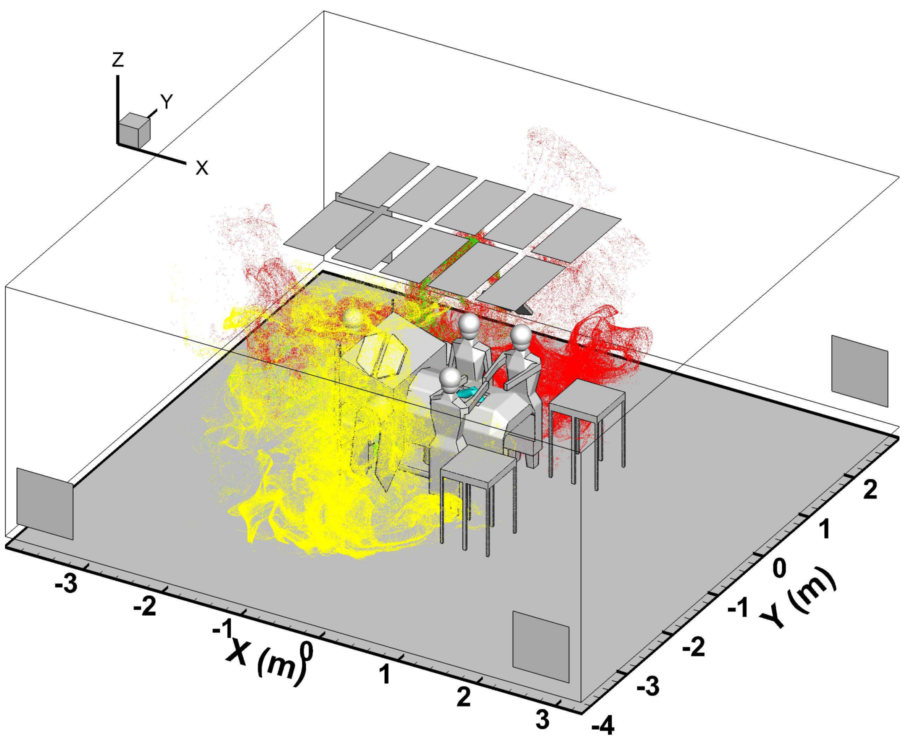


(b)

Figure 4: Instantaneous scatter plot of squames color-coded by their region of origin at 10s after initiation: (a) blower-off, (b) blower-on.

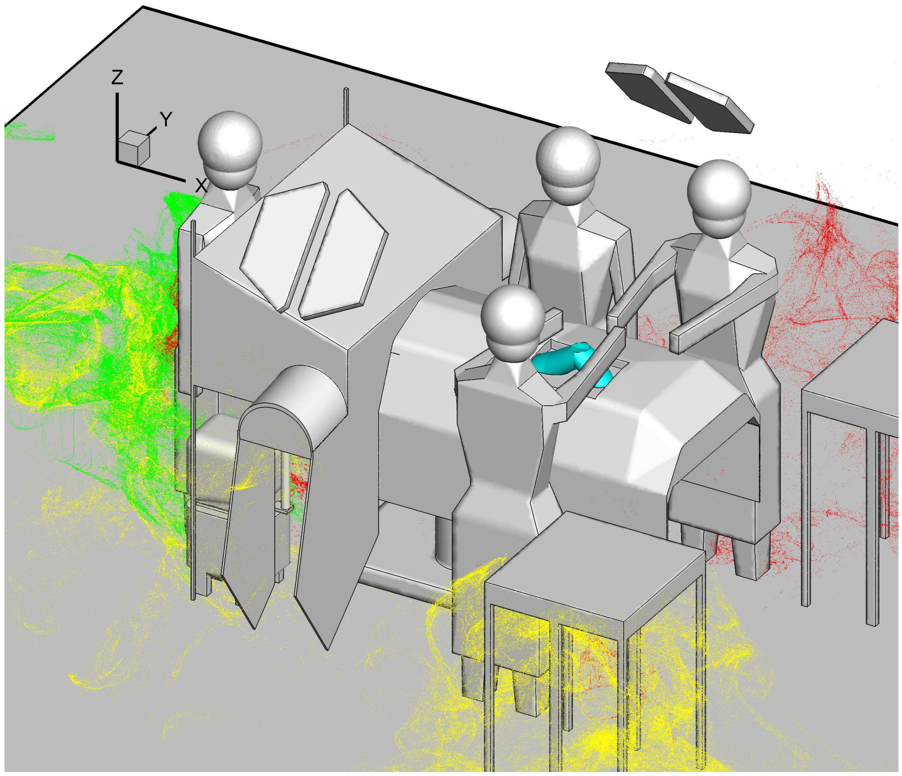


(a)

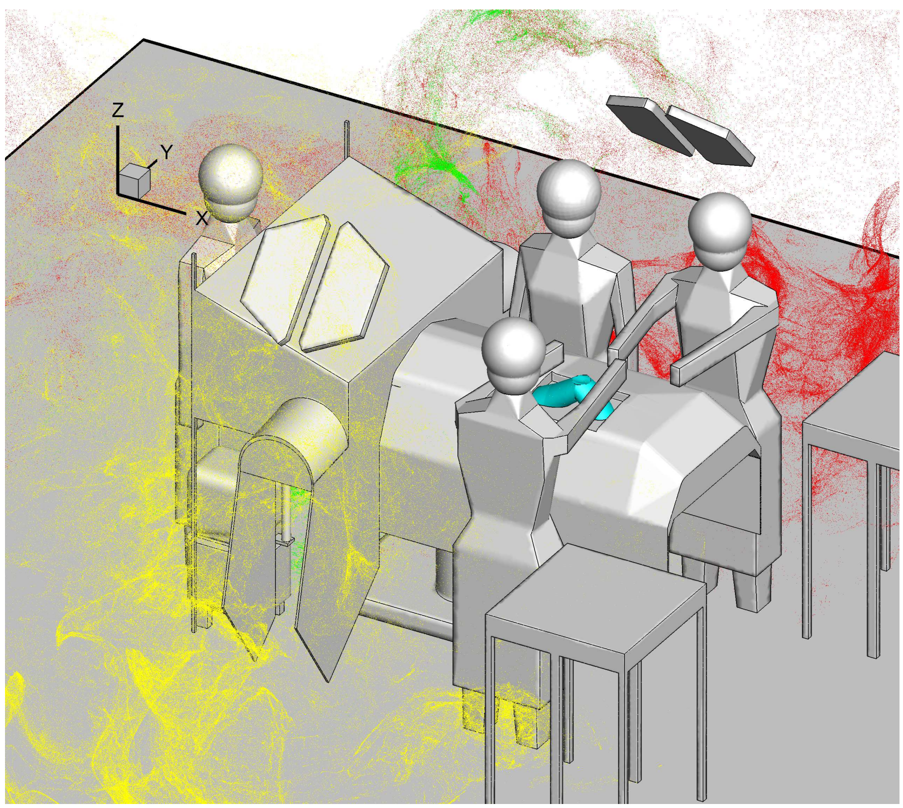


(b)

Figure 5: Instantaneous scatter plot of squames color-coded by their region of origin at 20s after initiation: (a) blower-off, (b) blower-on.



(a)



(b)

Figure 6: Zoom-in of the instantaneous scatter plot of squames color-coded by their region of origin at 20s after initiation: (a) blower-off, (b) blower-on.

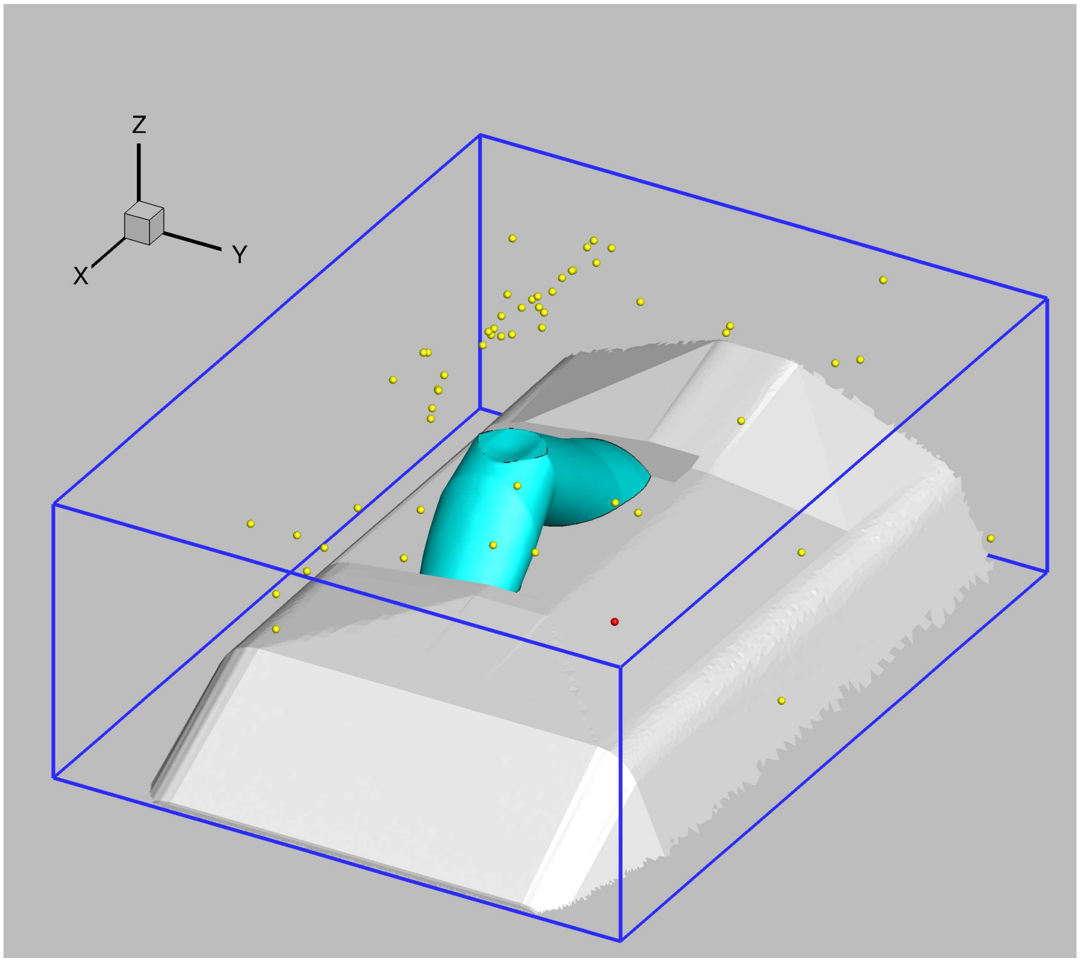


Figure 7: Zoom-in showing the instantaneous snapshot of squames near the surgical site at $t = 36$s.

3.2 Number density of squames in the regions of interest

Similar to the BH750 study, in order to evaluate the probability of squames reaching the surgical site, four *imaginary boxes* were located as follows: two boxes covering the two side tables, a box around the OT, and a box around the patient's knee area. The surgeons and medical assistants are bound to use surgical instruments placed on the side tables. The possibility of squames reaching the surgical site is then dependent on the number density of squames within these four imaginary boxes (see figure 8). The number of squame particles inside the four boxes were recorded in time. A blue box (figure 8 (a) and (c)) covers the whole OT including the patient's body and the surgeons hands. The height of the box is about 30 cm above the OT. An orange box (figure 8 (b) and (d)) is placed above the OT, just covering the patient's knee and part of the surgeon's hands; and the top of the box is only 2 cm above the surgeon's hands. One purple box (figure 8 (a) - (d)) is placed on each of the two side tables. The height of these boxes is about 1 cm, so that any surgical instrument placed on the side tables would be within the box.

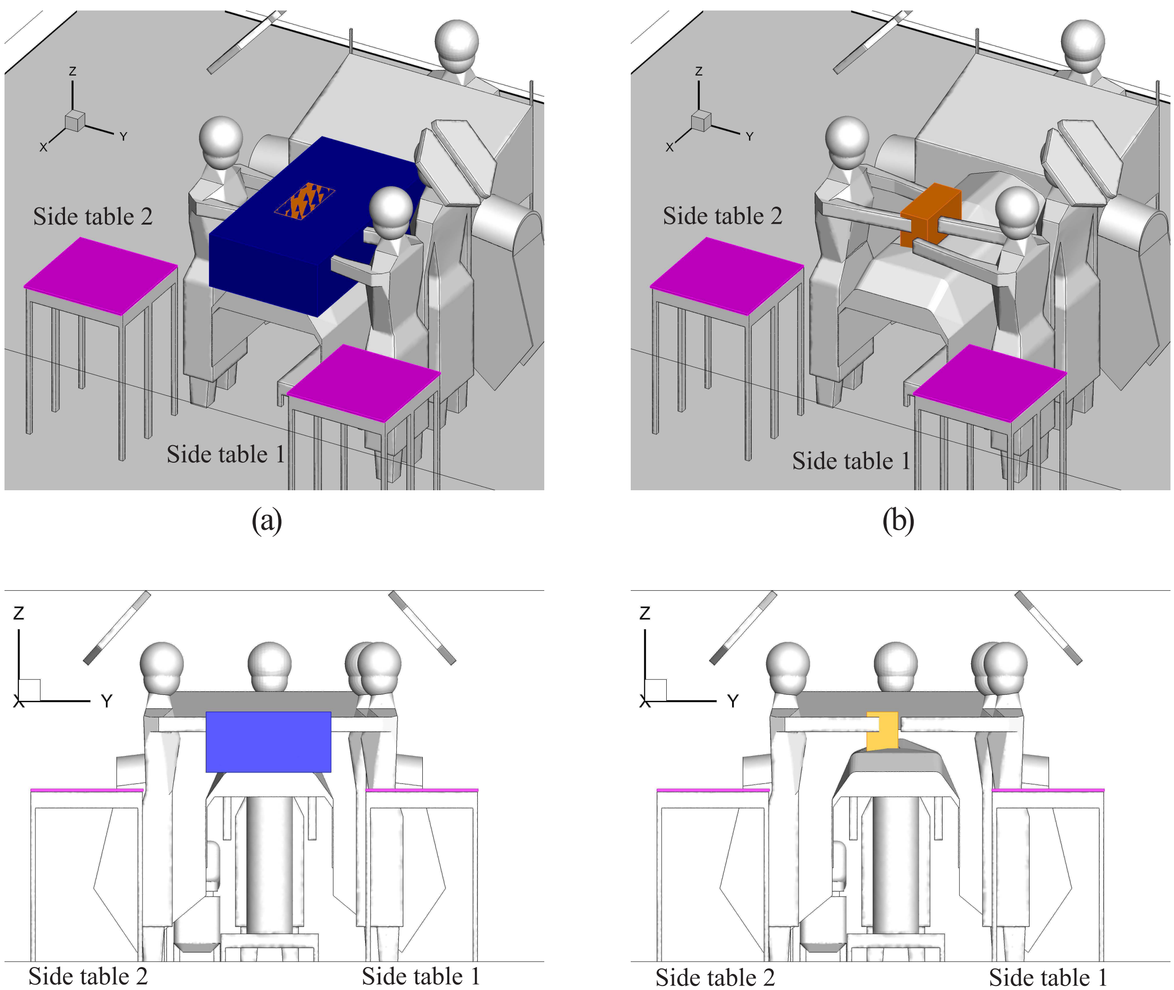


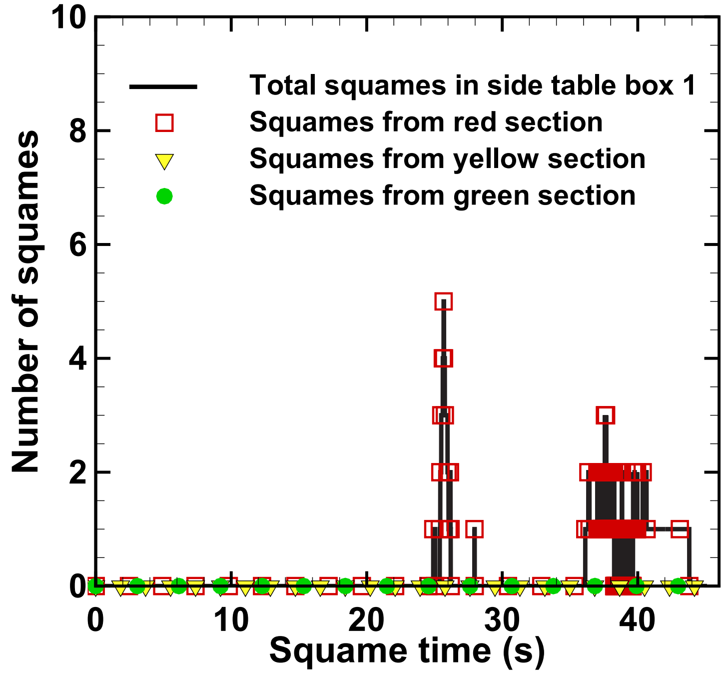
Figure 8: Four color-coded regions of interest, for recording the temporal history of the number of squames reaching them, shown in different views (a–d). The regions of interest include the zones above the two side tables, above the OT, and above the patient's knee.

With the blower turned on, the computations were carried out for about 45s of physical time

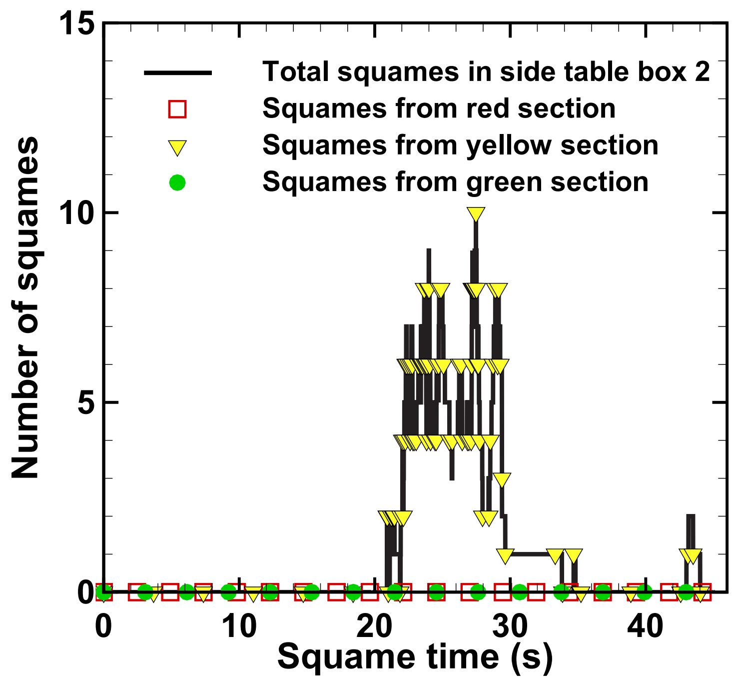
to obtain a flow field with well established thermal plumes created by the hot air discharged from the blower. After reaching a stationary state, the squames were initiated in the color-coded zones described earlier in section 2.2 and the computation continued for another 45s. With the blower on, hot air is discharged through the perforations of the blanket covering the patient's arms and chest, then passes under the drape surface into the ambient air. The difference between the temperatures of the hot air and the ambient air creates thermal plumes that rise under and around the operating table. Most of the squame particles are transported away from the OT towards the outlet grilles. However, a statistically significant number of particles are lifted above the operating table with some even reaching the height of the surgeons. The particles are carried upwards by the turbulent thermal plumes (eddies) until they get flushed down onto the operating table by the incoming ventilation air from the inlet grilles. The particles then do enter the imaginary boxes of interest, especially those above the operating table and the patient's knee.

Figures 9 and 10 show the number of squame particles as a function of time entering the four imaginary boxes of interest (above the two side tables, the operating table, and patient's knee). It can be seen from Figure 10b that no particles are found inside these boxes for the first 17s. This arrival-delay time is explained as follows. Figure 11 shows a snapshot of the velocity distribution video at about 15s after turning the BH505 blower on. This is the time needed to create a stagnation zone (where the air velocity ~ 0) at about 1.6m above the floor. A stagnation zone is created by the interaction of the rising hot air and the downward moving ventilation (cold) air. Once a particle reaches that zone it will start to fall due to gravity and then is entrained by the downward moving ventilation air. The air velocity near the floor (where the squames originate) is created by the entrainment of the ambient air by the thermal plume. The video shows that the air velocity there is about 0.1m/s. That is the velocity of the air surrounding the squames. Thus the time needed by the squame particle to rise to the stagnation zone = 1.6m/ (0.1 m/s)= 16 seconds. Then the particle needs few seconds to fall into the box. This gives approximately the time in Fig. 10b for the squames to start accumulating in the box. After this time, the number of squame particles in the box above the OT increases almost in a linear fashion. Within 36s of physical time, the number of squame particles within the OT box are at maximum of about 1500 and then start decreasing. Figure 10a shows that at about 30s, some of the particles above the OT start to enter the box above the knee, which is a very narrow zone surrounding the patient's knee. The number of these particles increases linearly to about 65. It is also interesting to note that the squame particles entering the box above the OT and above the knee are mainly the yellow-colored particles that originated near the side table 2 (see Fig. 1). Owing to the asymmetry in the CAD model geometry, the flow pattern around each side of the table is different and the recirculation region created by the incoming air from the inlet grilles is also asymmetric. The rise and eventual trapping of the squames within the knee box is thus also related to which side of the table it originated from. The boxes above the side tables also entrain about 5–10 squame particles as can be seen from Figures 9a,b. This suggests that there is a probability for the surgical instruments on the side tables to carry squames to the surgical site.

It is noted that all the figures of the squames temporal history show that the number of squames entering the four zones of interest (Fig. 8) reaches a peak then declines in time (Figures 9, 10). The reason is that only 3 million squames were used in the present study. Thus, after they reach a certain elevation where the stagnation zones exist they are flushed down by the ventilation air where they eventually leave the OR via the four outlet grilles. However, it is known [(2), (3)] that a person sheds about 500 million squames per day or about 21 million squames per hour. Thus, for the five persons (four medical staff and the patient) in the OR a realistic number would be about 105 million squames per hour. That number would provide a continuous supply of squames to the zones of interest and delay the decay observed in the temporal history curves.

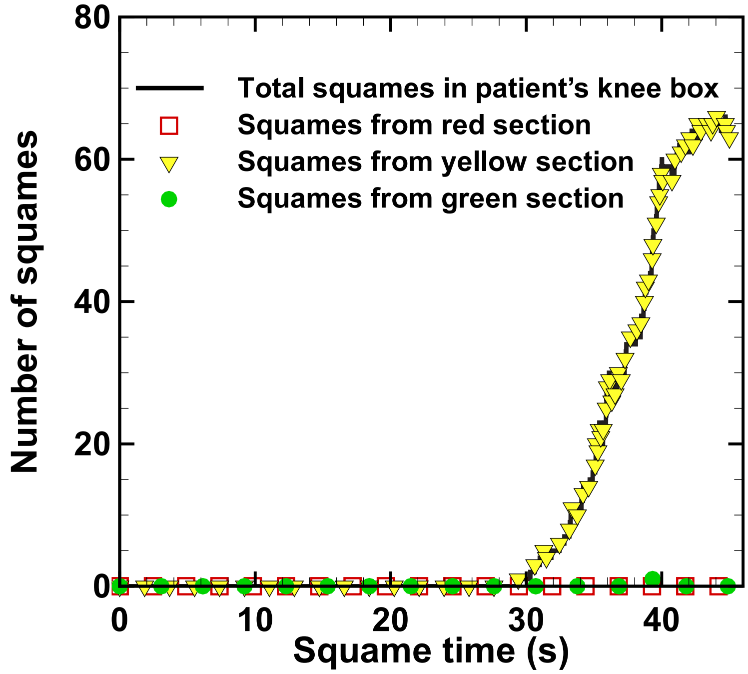


(a)

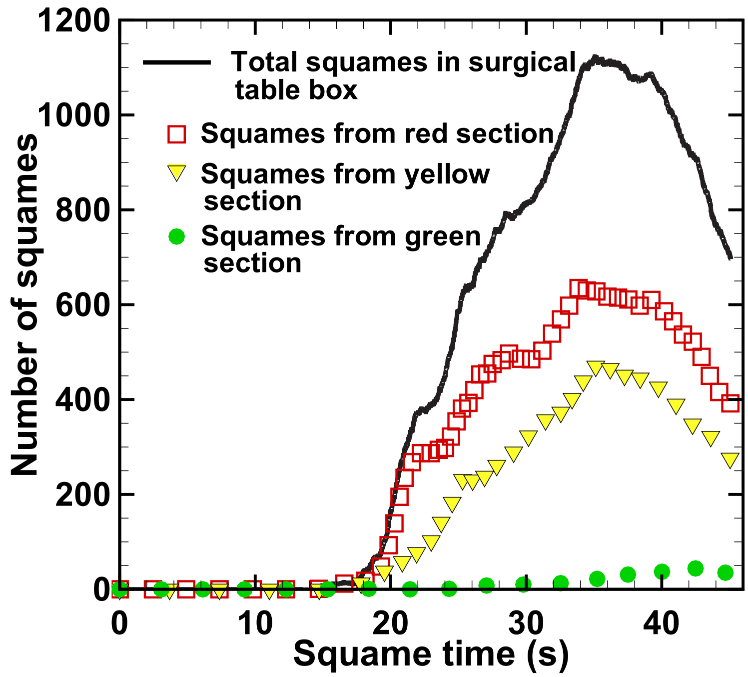


(b)

Figure 9: Temporal history of the total number of squames (shown by black color) entering four different regions of interest: (a) side table box 1, and (b) side table box 2. Also shown in color is the number of color-coded squame particles originating from the red, green and yellow regions whose coordinates are given in Table 2.



(a)



(b)

Figure 10: Temporal history of the total number of squames (shown by black color) entering four different regions of interest: (a) the patient's knee area, and (b) the OT box. Also shown in color is the number of color-coded squame particles originating from the red, green and yellow regions.

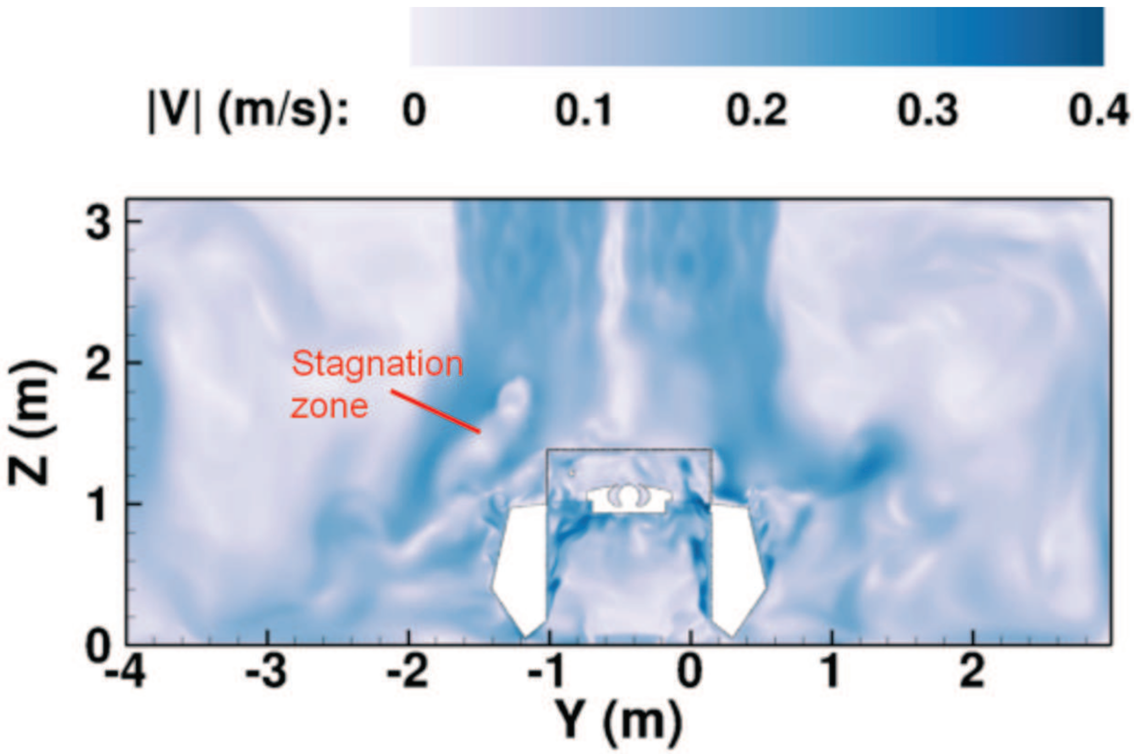


Figure 11: A snapshot of the velocity contours video at about 15s after turning the BH505 blower on

4 Summary

A high-fidelity, large-eddy simulation (LES) was performed to study the interaction of the operating room (OR) ultra-clean ventilation air flow and the flow created by a forced air warming system BH505. In this study, the blower flow rate was reduced by 32.57% as compared to the BH750 case. In addition, the temperature of the hot air flowing along the drape edge was reduced from 41.11° C to 39.73° C, a 3.35% decrease. Since the heated air temperature was not changed significantly, the net difference between the temperatures of the hot air and the ultra-clean ventilation air was nearly the same as in the BH750 case. This temperature difference (and the associated air density difference) is the source of the rising thermal plumes, and thus the strength of the rising plumes was not significantly affected. However, due to the lower flow rate of BH505, the velocity of the hot air along the drape was reduced (see Appendix A) and thus the time required for the the squames to disperse and reach the operating table and the surgical site was increased.

The results show that the general trends of squames dispersion observed in the BH750 study (1) were unchanged. With the blower off, none of the squame particles were found to enter the four imaginary boxes placed above the side tables, OT, and a region surrounding the patient's knee. Some particles were lifted from the floor over time, but none reached the level of the imaginary boxes as the downward flow due to the ventilation air keeps the particles closer to the floor. With the blower turned on, hot air discharged from the edges of the drape and the resultant thermal plumes drag the squames upwards. Some of the squames rise above the surgeons heads in the recirculation region on the sides of the OT. Once the particles reach a stagnation zone they are flushed down onto the OT by the ventilation air from the inlet grilles. Statistically significant number of particles do enter the imaginary boxes of interest above the operating table and the patient's knee. Few particles are also observed above the side tables. The time required for the particles to reach these imaginary

boxes was increased owing to the lower flow rate used in the present study. The number of squames reaching each box was also slightly lower than those observed in the previous case with high flow rate.

A Calculation of velocity and temperature of heated air leaving the BH blanket with Blower Model 505

The objective of this Appendix is to calculate the velocity and temperature of heated air as it leaves the BH blanket and enters the OR. In order to calculate the air temperature we need to calculate the heat transfer rate from the air to the patient's chest and arms. Since the heat transfer between the air and body occurs by forced convection, then we need to compute the velocity of the air as it moves between the BH blanket (with Blower Model 505) surface and the body.

A.1 Velocity of heated air leaving the BH blanket

Figure 12 shows the planar geometry of the BH blanket Model 522 before inflating it.

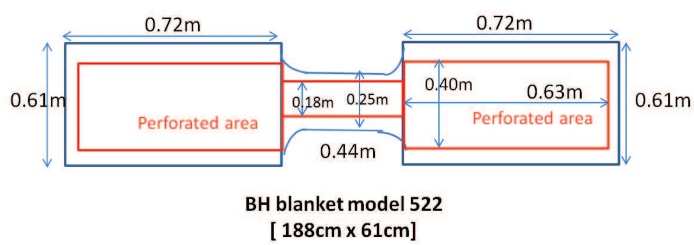


Figure 12: BH blanket geometry before inflation

In order to calculate the velocity of the air leaving the blanket we should consider the shape of the inflated blanket when it is connected to the BH blower as shown in Fig.13.

Figure 13: BH Inflated blanket. The dimensions with the red arrows are for PDF scaling only.

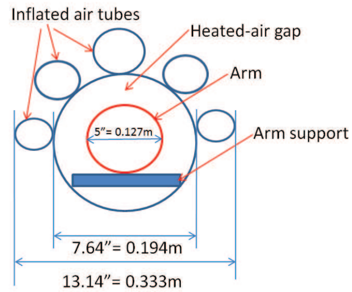


Figure 14: BH cross-section of inflated blanket

Fig.14 shows a cross-section of the inflated blanket after being wrapped around the arm.

The diameter of the cylindrical surface facing the arm $=0.194m$ which when unwrapped flat would produce the width of the blanket $(=0.61m)$ as shown in Fig.12, according to $L=\pi D$. The width of the heated-air gap between the arm and the blanket surface $= \frac{(0.194-0.127)}{2} = 0.0335m$.

The heated air issuing from the blanket holes (one thousand holes, each 1mm diameter) leaves the blanket across that gap on the right and left arms.

The total cross-sectional area of both the right and left gaps $= 0.0335 \times 0.61 \times 2 = 0.04087m^2$.

Thus, **the velocity of air leaving the right and left arms=**

$$\frac{\text{Blower505 volumetric flow rate}}{\text{gap area}} = \frac{0.01416\,\text{m}^3/\text{s}}{0.04087\,\text{m}^2} = \mathbf{0.3465}\,\text{m}/\text{s}$$

It should be noted that this is the velocity *before the air reaches the drape* that covers the blanket. The air will then leave the drape edges at a lower velocity as shown in Fig.15.

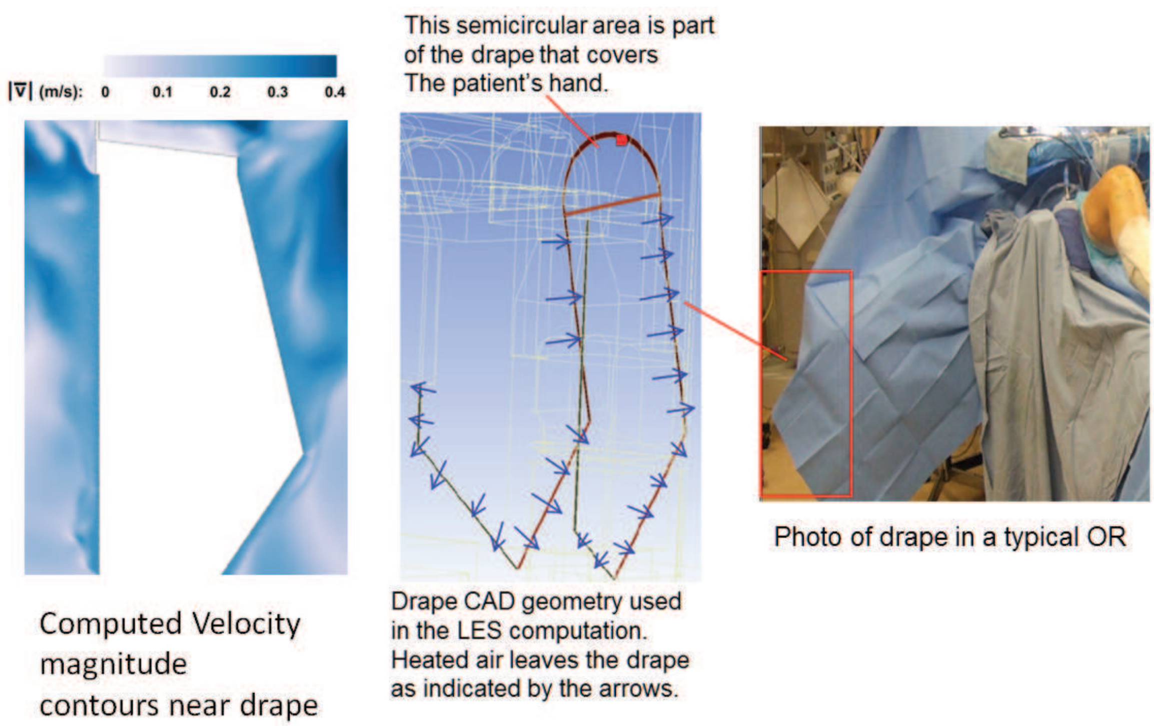


Figure 15: Drape geometry and heated air velocity near the drape.

A.2 Temperature of heated air leaving the BH blanket

In order to calculate the exit air temperature we apply the First Law of Thermodynamics to the control volume shown in Fig.16. For a steady-state condition we have:

$$\dot{m}_{in}\, h_{in} = \dot{m}_{exit}\, h_{exit} + \dot{q}_{body}\,, \qquad (1)$$

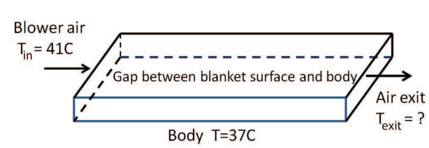


Figure 16: Schematic for heat transfer from air to body

where
$\dot{m}_{in}$= mass flow rate of blower air (kg/s)
$=$ air density $\times$ volumetric flow rate $= 1.127 \times 0.01416 = 0.01596$ kg/s ,
$\dot{m}_{exit}$= $\dot{m}_{in}$= $\dot{m}$ = mass flow rate of air leaving the blanket = 0.01596 kg/s,
h_{in}= enthalpy of air from the blower (kJ/kg),
h_{exit}= enthalpy of air leaving the blanket (kJ/kg),
$\dot{q}_{body}$ = rate of convective heat transfer from the air to the body (kJ/s= KW).
Since $\dot{m}$ is constant, Eq.(1) can be recast as:

$$h_{in} = h_{exit} + \dot{q}_{body}/\dot{m}, \tag{2}$$

The inlet enthalpy, h_{in}, is obtained from Thermodynamics Tables of air (e.g. (5), page 660) at the temperature of 40.5C. The Table gives $h_{in} = 313.5\,\mathrm{kJ/kg}$. Our goal is to find h_{exit} since it will give us T_{exit} via Thermodynamics Tables of air. Thus, we must first calculate the heat transfer to the body, $\dot{q}_{body}$.
Since the heat transfer from the air to the body is by forced convection, we have

$$\dot{q}_{body} = h_c \times \text{Area of blanket surface} \times (\mathrm{T_{air}} - \mathrm{T_{body}}) \ , \tag{3}$$

where h_c is the coefficient of convective heat transfer from air to body. This coefficient depends on the air velocity that was calculated in the previous subsection as $0.3465\,m/s$. Reference (4) provides experimental data of the heat transfer coefficient to the chest of a human as a function of the air velocity according to: $h_c = 9.1 \times V^{0.59}$. For a velocity $V = 0.3465\,m/s$, $h_c = 4.8689\,W/m^2K$.
The temperature difference is $T_{air} - T_{body} = (40.5 + 273.15) - (37 + 273.15) = 3.5K$.
The area of the blanket surface delivering the heated air is marked by the red contours in Fig.12: Area=$2(0.63 \times 0.4) + (0.44 \times 0.18) = 0.5832\mathrm{m}^2$. Substitution in Eq.(3) gives:

$$\dot{q}_{body} = 4.8689\,\mathrm{W/m^2K} \times 0.5832\mathrm{m}^2 \times 3.5\mathrm{K} = 9.939\mathrm{W} \tag{4}$$

Substitution in Eq.(2) gives:

$$313.5\,\mathrm{kJ/kg} = \mathrm{h_{exit}} + 9.939\mathrm{W}/(1000 \times 0.01596\mathrm{kg/s}), \tag{5}$$

which results in $h_{exit} = 313.5\,\mathrm{kJ/kg} - 0.6227\,\mathrm{kJ/kg} = 312.9\,\mathrm{kJ/kg}$.
Using this value of h_{exit}, and the Tables in (5), page 660, gives $\mathbf{T_{exit}} = \mathbf{39.73\,C}$.

It should be noted that as the body temperature rises above 37C due to the continuous (e.g. for one hour) heating by air, the value of $\dot{q}_{body}$ will be reduced, and the exit air temperature T_{exit} will approach 40.C asymptotically.

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